

AMENDMENTS TO THE CLAIMS

This following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (withdrawn-currently amended): A method for transfecting a polynucleotide into cells, the method comprising:

combining:

_____ (i) at least one polynucleotide;

_____ (ii) a cationic lipid, a cationic polymer or a dendrimer, or a combination thereof; and

_____ (iii) a solubilized cholesterol preparation

_____ to form a transfection composition; and

applying the transfection composition of claim 57 to cells, such that the cells are transfected with the polynucleotide.

Claim 2 (canceled)

Claim 3 (withdrawn-currently amended): The method of claim [[2]] 1, wherein the cyclodextrin is methyl- β -cyclodextrin.

Claim 4 (withdrawn-currently amended): The method of claim [[2]] 1, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-

beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

Claim 5 (withdrawn): The method of claim 1, wherein (ii) is a cationic lipid which is DOTAP.

Claim 6 (withdrawn): The method of claim 1, wherein (ii) is a dendrimer which is Superfect.

Claim 7 (withdrawn): The method of claim 1, wherein (ii) is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

Claim 8 (withdrawn): The method of claim 1, wherein the polynucleotide is plasmid DNA.

Claim 9 (withdrawn): The method of claim 1, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

Claim 10 (withdrawn): The method of claim 1, wherein the cells are eukaryotic cells.

Claim 11 (withdrawn): The method of claim 10, wherein the cells are mammalian cells.

Claim 12 (withdrawn): The method of claim 11, wherein the cells are urothelial cells.

Claim 13 (withdrawn): The method of claim 1, wherein the transfection composition is applied to cells in culture.

Claim 14 (withdrawn): The method of claim 1, wherein the transfection composition is applied to cells *in vivo*.

Claim 15 (withdrawn): The method of claim 12, wherein the transfection composition is applied to urothelial cells *in vivo* by intravesical delivery to a bladder of a subject.

Claim 16 (withdrawn-currently amended): In a method for transfecting a polynucleotide into cells wherein the polynucleotide is complexed with a cationic lipid, a cationic polymer or a dendrimer, said method comprising and applied applying the transfection composition of claim 57 to said cells, the improvement comprising formulating the polynucleotide and the cationic lipid, cationic polymer or dendrimer with a solubilized cholesterol preparation, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

Claim 17 (canceled)

Claim 18 (withdrawn-currently amended): The method of claim [[17]] 16, wherein the cyclodextrin is methyl- β -cyclodextrin.

Claim 19 (withdrawn-currently amended): The method of claim [[17]] 16, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

Claim 20 (withdrawn): The method of claim 16, wherein the cationic lipid is DOTAP.

Claim 21 (withdrawn): The method of claim 16, wherein the dendrimer is Superfect.

Claim 22 (withdrawn): The method of claim 16, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

Claim 23 (withdrawn): The method of claim 16, wherein the polynucleotide is plasmid DNA.

Claim 24 (withdrawn): The method of claim 16, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

Claim 25 (withdrawn): The method of claim 16, wherein the cells are eukaryotic cells.

Claim 26 (withdrawn): The method of claim 25, wherein the cells are mammalian cells.

Claim 27 (withdrawn): The method of claim 26, wherein the cells are urothelial cells.

Claim 28 (withdrawn-currently amended): The method of claim 16, wherein the ~~polynucleotide~~ transfection composition is applied to cells in culture.

Claim 29 (withdrawn-currently amended): The method of claim 16, wherein the ~~polynucleotide~~ transfection composition is applied to cells *in vivo*.

Claim 30 (withdrawn-currently amended): The method of claim 27, wherein the ~~polynucleotide~~ transfection composition is applied to urothelial cells *in vivo* by intravesical delivery to a bladder of a subject.

Claim 31 (withdrawn-currently amended): A method for delivering a ~~pharmaceutical agent~~ polynucleotide into urothelial cells of a subject, the method comprising:

~~combining the pharmaceutical agent with a solubilized cholesterol preparation to form a pharmaceutical composition; and~~

delivering ~~the pharmaceutical composition~~ a transfection composition according to claim 57 intravesicularly into the bladder of the subject, such that the ~~pharmaceutical agent~~ polynucleotide is delivered into urothelial cells of the subject.

Claim 32 (canceled)

Claim 33 (withdrawn-currently amended): The method of claim ~~[[32]]~~ 31, wherein the cyclodextrin is methyl- β -cyclodextrin.

Claim 34 (withdrawn-currently amended): The method of claim ~~[[32]]~~ 31, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

Claim 35 (canceled)

Claim 36 (withdrawn-currently amended): The method of claim ~~[[35]]~~ 31, wherein (ii) is a cationic lipid which is DOTAP.

Claim 37 (withdrawn-currently amended): The method of claim ~~[[35]]~~ 31, wherein (ii) is a dendrimer which is Superfect.

Claim 38 (withdrawn-currently amended): The method of claim [[35]] 31, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

Claim 39 (withdrawn-currently amended): The method of claim [[35]] 31, wherein the polynucleotide is plasmid DNA.

Claim 40 (withdrawn-currently amended): The method of claim [[35]] 31, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

Claim 41 (withdrawn-currently amended): A method for treating bladder cancer in a subject, the method comprising:

~~combining a pharmaceutical agent with a solubilized cholesterol preparation to form a therapeutic composition, wherein the pharmaceutical agent has anti-cancer activity against bladder cancer cells; and~~

~~delivering the therapeutic composition~~ transfection composition of claim 57
intravesicularly into the bladder of a subject, such that bladder cancer cells of the subject are ~~treated~~ transfected with the ~~pharmaceutical agent~~ polynucleotide, wherein the polynucleotide imparts anti-cancer activity against bladder cancer cells.

Claim 42 (canceled)

Claim 43 (withdrawn-currently amended): The method of claim [[42]] 41, wherein the cyclodextrin is methyl- β -cyclodextrin.

Claim 44 (withdrawn-currently amended): The method of claim ~~[[42]]~~ 41, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

Claim 45 (canceled)

Claim 46 (withdrawn-currently amended): The method of claim ~~[[45]]~~ 41, wherein (ii) is a cationic lipid which is DOTAP.

Claim 47 (withdrawn-currently amended): The method of claim ~~[[45]]~~ 41, wherein (ii) is dendrimer which is Superfect.

Claim 48 (withdrawn-currently amended): The method of claim ~~[[45]]~~ 41, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

Claim 49 (withdrawn-currently amended): The method of claim ~~[[45]]~~ 41, wherein the polynucleotide comprises at least one expression vector encoding at least one protein selected from the group consisting of interleukins, interferons, colony stimulating factors, anti-angiogenic factors, anti-metastatic factors, membrane receptors and tumor suppressors.

Claim 50 (withdrawn-currently amended): The method of claim ~~[[45]]~~ 41, wherein the polynucleotide comprises an expression vector encoding a protein selected from the group consisting of interleukin-1 (IL-1), interleukin-2 (IL-2), interleukin-6 (IL-6), interleukin-9 (IL-9),

interleukin-11 (IL-11), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-18 (IL-18), interferon- α , interferon- β , interferon- γ , granulocyte-macrophage colony stimulating factor (GMCSF), granulocyte colony stimulating factor (GCSF), macrophage colony stimulating factor (MCSF), heat shock protein (HSP), p53, an antagonist of vascular endothelial cell growth factor (VEGF), a tissue inhibitor of metalloproteinases (TIMP), and a fibronectin receptor.

Claim 51 (withdrawn-currently amended): The method of claim [[45]] 41, wherein the polynucleotide comprises an expression vector encoding interleukin-2 (IL-2).

Claim 52 (withdrawn-currently amended): The method of claim [[45]] 41, wherein the polynucleotide comprises an expression vector encoding granulocyte macrophage colony stimulating factor (GMCSF).

Claim 53 (withdrawn-currently amended): The method of claim [[45]] 41, wherein the polynucleotide comprises an expression vector encoding interferon- γ .

Claim 54 (withdrawn-currently amended): The method of claim [[45]] 41, wherein the polynucleotide comprises at least one expression vector encoding two or more of interleukin-2 (IL-2), granulocyte macrophage colony stimulating factor (GMCSF) and interferon- γ .

Claim 55 (withdrawn): The method of claim 41, which further comprises performing an additional anti-bladder cancer treatment on the subject.

Claim 56 (withdrawn): The method of claim 55, wherein the additional anti-bladder cancer treatment comprises Bacillus Calmette-Guerin (BCG) therapy.

Claim 57 (currently amended): A transfection composition comprising:

(i) a polynucleotide;

(ii) a cationic lipid, a cationic polymer or a dendrimer, or combinations thereof; and

(iii) a solubilized cholesterol preparation, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

Claim 58 (canceled)

Claim 59 (currently amended): The transfection composition of claim [[58]] 57, wherein the cyclodextrin is methyl- β -cyclodextrin.

Claim 60 (currently amended): The transfection composition of claim [[58]] 57, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

Claim 61 (original): The transfection composition of claim 57, wherein (ii) is a cationic lipid which is DOTAP.

Claim 62 (original): The transfection composition of claim 57, wherein (ii) is a dendrimer which is Superfect.

Claim 63 (original): The transfection composition of claim 57, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

Claim 64 (original): The transfection composition of claim 57, wherein the polynucleotide is plasmid DNA.

Claim 65 (original): The transfection composition of claim 57, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.